K021004

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JUN 6 2002

medamicus
INCORPORATED

V. 510(k) Summary

Submitter

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Submission Contact

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Date Prepared

February 28, 2002

Trade Name

Valved Peelable Introducer

Common Name

Catheter Introducer

Classification Name

Introducer, Percutaneous

Predicate Device

MedAmicus Percutaneous Introducer, K932323
MedAmicus Percutaneous Introducer, Material Change K000824

Device Description Information

Device Description

The MedAmicus Valved Peelable Introducer package consists of a thin-wall needle, a disposable syringe, and a flexible guidewire, packaged in a tray and a sealed pouch. Percutaneous introducers are small diameter tubular shaped devices with integrated proximal handles. The Valved Peelable Introducer is designed to provide a relatively atraumatic method for implanting catheters and pacemaker leads into the venous system. The Valved Peelable Introducer has a "tear-away" feature common to the predicate devices. This feature allows the user to remove the introducer without removing the inserted catheter or pacing lead.

The Valved Peelable Introducer includes a sliding valve. When the valve is slid over the proximal end of the sheath, a device may be passed through the valve into the sheath, providing for reduced blood loss and reduced risk of air intake. The valve may be slid so that it is not covering the opening to the inner diameter of the sheath as well. The valve is constructed of a piece of silicon which snaps into a valve 'body' constructed of molded components.

Materials

The materials used in the manufacture of the Valved Peelable Introducer are identical to the materials used in the predicate device; with the exception of the valved portion of this introducer. All materials have been tested for biocompatibility.

The sheath body is constructed of PTFE and is filled with bismuth trioxide as a radiopacifier. The handles, made of TPX resin, are overmolded onto the PTFE sheath tubing. The dilator is made of HDPE resin filled with barium sulfate as a radiopacifier and has a HDPE hub overmolded onto the dilatory shaft.

The silicone part material is liquid silicone rubber. The permanent coating is parylene-N. The silicone lubricant is a mixture of Dow 360 Medical Fluid and Hexanes.

The Valved Peelable Introducer will be packaged and EtO sterilized for one time use in a Tyvek pouch with a guidewire, needle and syringe. This configuration and specification remains the same as the configuration and specification that was previously cleared under K932323 and K000824.

The Polystyrene tray is commonplace in the medical industry as a packaging material for a number of medical devices. Biocompatability evaluations have

been conducted along with sterility testing which demonstrate that this material is suitable as a tray material.

Appendix A contains photographs and engineering drawings of the Valved Peelable Introducer.

Appendix B contains a kit certification statement as required by FDA.

This percutaneous introducer has been modified from the introducer cleared under K932323. The material for the sliding valve portion of the introducer has been modified from polypropylene to silicone. The purpose of this change is to add the functionality of allowing a device to pass through the valve. The originally cleared product included a sliding valve that had to be slid out of the way when a device was inserted.

Device Sizes
Sizes of the sheath and dilator range from 7FR to 16FR. The materials and construction are the same for all French sizes.

French	Sheath Length ±.50
7	5.93
7L	5.86
8	5.93
9	5.93
10	5.93
11	5.93
12	5.93
13	5.93
14	5.53
15	5.53
16	5.53

Intended Use

The Valved Peelable Introducer is indicated for use in the percutaneous insertion of pacing leads or catheters in the venous system.

Technological Characteristics

The device is technologically equivalent to other introducers, including the valve mechanism to reduce blood loss and the risk of air intake.

Comparison to Predicate Device(s)

The Device Comparison Chart, Figure 1 below, shows that the Subject Device is equivalent to the two Predicate Devices. The Intended Use statements are identical and the design features are similar. The MedAmicus Valved Peelable Introducer is substantially equivalent to the MedAmicus Introducer Percutaneous, Valved, K932323, cleared November 9, 1993 in combination with the Material Change, Percutaneous Introducer K000824, cleared April 13, 2000.

Device Comparison Chart

	Subject Device	Predicate Device	Predicate Device
	MedAmicus Valved Peelable Introducer	MedAmicus Introducer, Percutaneous, Valved K932323	MedAmicus Material Change, Percutaneous Introducer K000824
Intended Use	The MedAmicus Valved Peelable Introducer is intended for use in the percutaneous insertion of pacing leads or catheters in the venous system.	The MedAmicus Percutaneous Introducer is indicated for use in the insertion of pacing leads or catheters in the venous system.	The MedAmicus Percutaneous Introducer is indicated for use in the insertion of pacing leads or catheters in the venous system.
Design Features	PTFE Introducer sheath with sliding valve to reduce the risk of blood loss and minimize the risk of air intake. Devices may be inserted through the valve.	Introducer sheath with a sliding valve to reduce the risk of blood loss and air aspiration	Introducer Sheath and Dilator only

Figure 1

Summary of Studies

A Risk Analysis for the Valved Peelable Introducer was performed per MedAmicus' internal procedure, WI42020, *Hazard Analysis, FMEA and Risk Analysis*. This document is modeled closely after European Standard EN1441: 1998 *Medical Devices – Risk Analysis*.

The performance testing for this device included testing to verify that the valve portion functions per the design requirement. The remainder of the items (sheath, dilator, guidewire, syringe, and needle) have been tested under previously approved 510K's. The test results (see Figure 2 below) support the determination of substantial equivalence to the predicate device(s). This device will reduce the risk of blood loss and will minimize the risk of air intake. The following table includes the tests that have been conducted, the specifications of the tests and the results of each test:

Test	Sample Size	Specification	Min	% Reduction In Air Flow compared to he Introducer with the valve not closed Mean	Max
Valve Pressure Flowrate	30	Valve must reduce flow	90%	95% reduction (before device insertion)	99%
			78%	86% reduction (after dilator/guidewire removal)	94%
Valve Vacuum Flowrate	29	Valve must reduce flow	93%	96% reduction (before device insertion)	99%
			80%	88% reduction (after dilator /guidewire removal)	99%
			Force	Force	Force
Dilator Insertion Force	29	2.0 lb. maximum	0.47 lb.	0.66 lb.	1.03 lb.
Dilator Removal Force	29	2.0 lb. maximum	0.50 lb.	0.74 lb.	1.09 lb.
Catheter Insertion Force	29	2.0 lb. maximum	0.56 lb.	0.88 lb.	1.09 lb.
Valve Peeling Force	29	Valve must peel off catheter	Pass	Pass	Pass

Figure 2.

510(k) Summary Conclusion

Medamicus belives that the MedAmicus Valved Peelable Introducer is substantially equivalent to the predicate MedAmicus Percutaneous Introducer kits. The intended use, materials, sterilization, packaging, labeling, method of operation and manufacturing methods have been proven to be identical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 6 2002

MedAmicus, Incorporated
c/o Ms. Karyl D. Haskell
Quality Assurance and Regulatory Affairs Manager
15301 Highway 55 West
Minneapolis, MN 55447

Re: K021004
Trade Name: Valved Peelable Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: Class II (two)
Product Code: 74 DYB
Dated: March 27, 2002
Received: March 28, 2002

Dear Ms. Haskell:

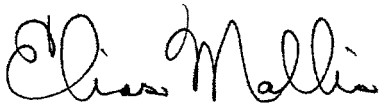
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4586. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



for Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

VII. Indications for Use

510(k) Number (if known): Not Assigned

Device Name: MedAmicus Valved Peelable Introducer

Indications for Use: The MedAmicus Valved Peelable Introducer is intended for use in the percutaneous insertion of pacing leads or catheters in the venous system.

Elsie Mallis

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K021004

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)